THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
at CHATTANOOGA

In re: SKELAXIN (METAXALONE) ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: **ALL ACTIONS**	Lead Case Nos.: 2:12-cv-83 2:12-cv-4 1:12-cv-194 1:12-cv-203 2:12-cv-464 MDL Case No: 1:12-md-2343 Judge Curtis L. Collier

DEFENDANTS' MEMORANDUM IN SUPPORT OF THE MOTION TO DISMISS PLAINTIFFS' COMPLAINTS

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INTRODUCTION

Plaintiffs assert antitrust claims alleging that Defendants King Pharmaceuticals LLC, f/k/a King Pharmaceuticals, Inc. ("King") and Mutual Pharmaceutical Company, Inc. ("Mutual") conspired to delay entry of a generic version of King's patented drug Skelaxin. Plaintiffs theorize that, but for Defendants' alleged wrongful conduct, a generic metaxalone tablet would have entered the market earlier, and in turn, they would have paid less for the drug. The dates of the hypothetical earlier entry vary -- 2005 or 2006 is alleged in most of the complaints, 2007 in another. The earliest complaint was not filed until January 2012.

While Plaintiffs' complaints certainly do not suffer from a shortage of words (each weighs in at over 300 numbered paragraphs and about 100 pages), what they provide in verbiage they lack in merit. Plaintiffs do not come close to advancing the types of specific factual allegations necessary to establish a viable antitrust claim under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007).

As described in more detail below, Skelaxin has been on the market for fifty years, but the events about which Plaintiffs complain all took place within a short window of time, principally between 2005 and 2007. However, Plaintiffs have not connected the allegedly actionable conduct to any actual delay in the entrance of generic Skelaxin to the market, and they cannot do so. Nor do Plaintiffs' allegations of alleged "sham" pass muster under *Twombly*. Plaintiffs' state law claims suffer as well from incurable infirmities. In any event, and dispositively, Plaintiffs' claims are time-barred under the various statutes pursuant to which they have been brought.

More specifically, Plaintiffs' complaints fail to state a plausible and viable claim for relief and the Court should dismiss them because:

1. Plaintiffs' federal joint conduct claims fail because they fail to plausibly allege that any of the challenged conduct caused Plaintiffs' actual injury. That is, they have not adequately alleged causation. Moreover, almost all of the challenged conduct was protected by the First Amendment.

2. The Tennessee Trade Practices Act claim filed by the indirect purchaser retail pharmacy Plaintiffs fails to allege facts showing that Defendants' allegedly wrongful conduct had "substantial effects" on Tennessee trade or commerce. These Plaintiffs expressly exclude from their asserted class all Tennessee retailers, and their claims concern only retailers and metaxalone sales outside of Tennessee.

3. The unjust enrichment claims brought under federal general common law fail because there is no such thing as a federal general common law claim of unjust enrichment. Moreover, state laws prohibit Plaintiffs from recasting antitrust and consumer protection allegations as state or federal law claims for unjust enrichment.

4. Plaintiffs' federal claims are barred by the Sherman Act's four-year statute of limitations, and virtually all of the state law claims are barred by the relevant state's limitations periods. Under Plaintiffs' own theory of the case, the statutes of limitations began to run in 2005 or 2007 at the latest, as these are the dates they allege generic metaxalone would have entered the market but for Defendants' allegedly wrongful conduct. Plaintiffs, however, did not file suit until 2012 -- more than five years after the limitations period began to run. While the complaints make brief references to conduct occurring within the alleged four-year Sherman Act limitations period (*i.e.*, after 2008), this post-2008 conduct cannot restart the limitations periods as a matter of law because that conduct could not have delayed the entry of generic metaxalone into the market.

5. Plaintiffs' conclusory assertions of fraudulent concealment do not provide an escape hatch from the relevant statutes of limitation. The acts of which Plaintiffs complain were matters of *public record* -- patent litigations, FDA citizen petitions, and an intellectual property license that was filed with the SEC and posted on the internet -- and thus cannot support a fraudulent concealment claim.

Plaintiffs' claims lack substantive merit on their face and, in any event, are barred by the applicable statutes of limitations. Consequently, the complaints should be dismissed.

SUMMARY OF STATUTORY FRAMEWORK

A. FDA Procedures for Gaining Approval to Market a Drug

The Food and Drug Administration ("FDA") must approve all pharmaceutical products before they are sold. 21 U.S.C. § 355(a). The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., sets forth the rules governing the FDA's approval of drugs.

1. New Drug Applications

To obtain approval for a new drug, an applicant must file a New Drug Application ("NDA") that proves the drug is safe and effective. 21 U.S.C. § 355(b)(1); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1045 (Fed. Cir. 2010) (detailing the drug approval process).

The NDA must include detailed safety and efficacy data on the drug. 21 U.S.C. § 355(b)(1). The NDA is also required to include the patent numbers and expiration dates of any patent (1) which claims the drug or methods of using the drug and (2) for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *Id.* The FDA publishes the names of approved drugs and their associated patent information in what is commonly called the "Orange Book." *AstraZeneca*, 633 F.3d at 1045. A drug with NDA approval is termed a Reference Listed Drug, commonly known as a "brand-name" drug. *See* 21 C.F.R. § 314.3.

2. Supplemental New Drug Applications

After NDA approval, a manufacturer seeking to change the brand-name drug or its label must file, and the FDA must approve, a supplemental New Drug Application ("sNDA"). 21 C.F.R. § 314.70(a)(1). An example of a change requiring a sNDA is where the brand-name manufacturer seeks to sell the drug in a different strength than the strength already approved in the NDA. 21 C.F.R. § 314.70(b)(1).

3. Abbreviated New Drug Applications

The Hatch-Waxman Amendments to the FDCA govern the FDA approval procedures for generic equivalents of previously approved brand-name drugs. *In re Wellbutrin XL Antitrust Litig.*, 2012 WL 1657734, at *1 (E.D. Pa. May 11, 2012); 21 U.S.C. § 355(j). A generic drug manufacturer can obtain FDA approval without filing an NDA; instead, it can file an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j). An ANDA applicant can rely on the safety and efficacy data for the brand-name drug if it can prove the generic drug is "bioequivalent" to the brand-name drug.[1] *AstraZeneca*, 633 F.3d at 1045; 21 U.S.C. § 355(j)(2)(A)(iv).

There are several other ANDA requirements relevant here. ***First***, the "route of administration, the dosage form, and the strength" of the generic drug must be the same as those of the brand-name drug (unless the FDA approves a "suitability petition" requesting permission to file an ANDA that differs in one or more of these respects). 21 U.S.C. § 355(j)(2)(A)(iii). ***Second***, the labeling for the generic drug must be the same as the labeling for the brand-name drug, subject to certain exceptions. 21 U.S.C. § 355(j)(2)(A)(v). ***Third***, the ANDA must make

[1] A generic drug is "bioequivalent" to a brand-name drug if the rate and extent of absorption of the generic drug is not significantly different from the brand-name drug when administered under similar experimental conditions. *See* 21 U.S.C. § 355(j)(8)(B).

one of the following certifications for each Orange Book-listed patent for the brand-name drug: (I) that the Orange Book lists no patent information for the brand-name drug; (II) that the listed patents have expired; (III) that the ANDA should not be approved until the listed patents expire; or (IV) that the listed patents are invalid or will not be infringed by the generic drug's manufacture, use, or sale. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). The last certification is commonly referred to as a "Paragraph IV Certification."

Applicants making a Paragraph IV Certification must provide the brand-name manufacturer with notice of the legal and factual basis for the certification. 21 U.S.C. § 355(j)(2)(B)(ii)(I). If the brand-name manufacturer sues the ANDA applicant for patent infringement within forty-five days of receiving the Paragraph IV Certification, final FDA approval of the ANDA is automatically stayed until the earliest of: (1) the date the patent expires; (2) the date (if any) the district court finds the patent is invalid or the generic to be non-infringing; or (3) thirty months after receipt of the notice. 21 U.S.C. § 355(j)(5)(B). This is commonly referred to as the "thirty-month stay." The thirty-month stay is ***not*** applicable if the patent that is the subject of the Paragraph IV Certification was issued ***after*** the ANDA was filed. *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1351 n.* (Fed. Cir. 2009).

For an Orange-Book-listed patent claiming a "method of use," an ANDA applicant can, instead of making a Paragraph IV Certification, file a "section viii statement" declaring that it is not seeking approval for a method of use covered by the patent. *AstraZeneca*, 633 F.3d at 1046; 21 U.S.C. §§ 355(j)(2)(A)(viii). A section viii statement requires "the applicant to remove or 'carve out' any mention of the patented method of use from the proposed label for the generic drug." *AstraZeneca*, 633 F.3d at 1046.

If the FDA finds that the generic drug satisfies the requirements for approval but final approval is blocked by the thirty-month stay or certain other legal barriers, the FDA may give the drug "tentative approval." 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA). Tentative approval of the generic drug does not permit it to be sold, or guarantee that FDA will grant final approval. 21 C.F.R. §§ 314.105(d), 314.107(b)(3)(v); *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 859 (D.C. Cir. 2008).

B. Citizen Petitions

Federal law invites any interested person to try to affect FDA action. 21 C.F.R. § 10.30; *Aventis Pharma. S.A. v. Amphastar Pharm., Inc.*, 2009 WL 8727693, at *2 (C.D. Cal. Feb. 17, 2009). "The FDA encourages this, maintaining an open invitation to the public to file a 'citizen petition.'" *Aventis*, 2009 WL 8727693, at *2. There are no limitations on the issues or scope of relief a citizen petition may raise. Any interested person may ask the FDA "to issue, amend or revoke a regulation or order; or to act or refrain from acting." *Id.*; 21 C.F.R. § 10.30(b). Citizen petitions are not adversary proceedings.

There are few fixed procedures for citizen petitions, but "the FDA invites comments" on each petition from interested persons who may file written comments supporting or opposing the petition in whole or in part. *Aventis*, 2009 WL 8727693, at *2; 21 C.F.R. § 10.30(d). Within 180 days of receiving a citizen petition, the FDA must approve, deny, or provide a tentative response indicating the reasons for its inaction. 21 C.F.R. § 10.30(e)(2); *In re Wellbutrin*, 2012 WL 1657734, at *2 & n.3. Since at least September 27, 2007, the FDA is not permitted to delay approval of an ANDA due to a pending citizen petition unless it finds a delay "is necessary to

protect the public health."[2] 21 U.S.C. § 355(q)(1)(A)(ii). *See also In re Wellbutrin*, 2012 WL 1657734, at *2 n.3; FDA Guidance for Industry, Citizen Petitions and Petitions for Stay of Action Subject to 505(q) of the *Federal Food, Drug, and Cosmetic Act*, at 4-5 (June 2011), *available at* http://1.usa.gov/Vl98KF (attached as *Exhibit* 1).[3]

The FDA maintains all citizen petitions, submissions relating to the petitions, and decisions on petitions in a file "available for public examination" at its Division of Dockets Management in Rockville, Maryland. 21 C.F.R. §§ 10.20(f), 10.20(*l*), 10.30(c), 10.30(e)(3).

FACTS ALLEGED BY PLAINTIFFS[4]

A. The Parties

Defendant King is a pharmaceutical company that sells the brand-name prescription drug Skelaxin®, a muscle relaxant with the active ingredient metaxalone. Direct Purchaser Class Complaint ("DPP Compl."), ¶ 18. Defendant Mutual develops, manufactures, and sells pharmaceutical drugs. *See id*., ¶¶ 79-81.

The proposed class of direct purchaser Plaintiffs ("DPPs") consists of companies, primarily wholesalers, that allegedly purchased Skelaxin directly from King. *See id.*, ¶¶ 13-17.

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[2] Even before 2007, the FDA's own regulations precluded delaying any action due to a citizen petition unless the FDA "determines that a stay or delay is in the public interest and stays the action." 21 C.F.R. § 10.35 (2005).

[3] References to "*Exhibit*" herein refer to those exhibits annexed to the Declaration of Jonathan S. Lawson, dated January 4, 2013.

[4] The allegations herein are drawn from the consolidated complaints filed by the three putative classes of purchasers, and the two non-class action complaints (*Walgreen* and *BCBS*). These allegations are accepted as true for purposes of this motion only. The "background" and "facts" sections of the three consolidated complaints are virtually identical, and the facts alleged in the consolidated complaints are similar to those alleged in the non-class action complaints. To avoid needlessly duplicative citations of three separate consolidated complaints and the two non-class action complaints, Defendants cite to the paragraph numbers in the complaint filed by the direct purchaser class Plaintiffs ("DPP Compl., ¶ __").

There is also a proposed class of indirect purchaser retail pharmacies ("IPPs") who call themselves the "indirect purchaser for resale" Plaintiffs. *See* Indirect Purchaser Consolidated Complaint ("IPP Compl."), ¶¶ 12-15. A second proposed indirect purchaser class, consisting primarily of insurance companies and health and welfare benefit funds, claims to have paid for all or part of the purchase price of Skelaxin dispensed to their members or insureds; they call themselves the "end payor" Plaintiffs ("EPPs"). *See* End Payor Consolidated Complaint ("EP Compl."), ¶¶ 8-13.[5] Finally, the five Plaintiffs in *Walgreen v. King* ("*Walgreen* Plaintiffs") -- the non-class action case consolidated in this MDL -- are large retail chain stores, each of which is a member of the IPP retail pharmacy class as well as an assignee of the largest wholesalers in the DPP class. *See* Walgreen Complaint ("Walgreen Compl."), ¶¶ 12-16.

B. Plaintiffs' Theory of the Case: But for the Alleged Anticompetitive Conduct, Generic Metaxalone Would Have Been Available by 2005 or 2007

Plaintiffs allege that King and Mutual conspired to exclude potential generic competition for Skelaxin. In summary, the complaints allege that: (1) King engaged in "sham" patent infringement litigation against potential generic competitors to enforce three patents covering Skelaxin that were later invalidated; (2) King unlawfully listed and maintained these three patents in the Orange Book; (3) King and Mutual filed "sham" citizen petitions with the FDA;

[5] Plaintiffs BlueCross BlueShield of Tennessee and Painters District Council No. 30 Health and Welfare Fund (the "*BCBS* Plaintiffs"), *see BlueCross BlueShield of Tenn., Inc., et al. v. King Pharm., Inc., et al.*, Case No. 2:12-cv-00464 (E.D. Tenn.), were originally part of the EPP class but voluntarily dismissed their complaint on November 2, 2012, and re-filed a complaint asserting the same essential claims in the Circuit Court for Cocke County, Tennessee, on that same day. Defendants timely removed the *BCBS* Plaintiffs' action to this Court on December 5, 2012, and then filed a Notice of Potential Tag-Along with the Judicial Panel on Multi-District Litigation on December 11, 2012, notifying the Panel that the BCBS action should be returned to MDL 2343. Indeed, although the *BCBS* Plaintiffs are not named in the EPPs' consolidated complaint, they are members of the EPP class. Therefore, all arguments in the complaint advanced against the EPPs are equally applicable with respect to the *BCBS* Plaintiffs. For ease of reference, this Memorandum will simply refer to the EPPs.

and (4) Mutual entered into an agreement (the "2005 License Agreement") not to market its own generic metaxalone product and to help King keep potential generic competitors off the market. *See* DPP Compl., ¶¶ 2-11.

The class action Plaintiffs claim that but for the allegedly wrongful conduct, generic metaxalone would have been on the market by November 4, 2005. *Id*., ¶¶ 257, 263-64. The *BCBS* Plaintiffs and *Walgreen* Plaintiffs contend that generic entry would have occurred in 2006 or 2007. BCBS Compl., ¶ 114; Walgreen Compl., ¶ 226.

C. The Alleged Sham Patent Infringement Litigations and Unlawful Listing of Patents in the Orange Book by King from 2002-2006

The FDA originally approved Skelaxin for sale in 1962. DPP Compl., ¶ 69. The patent that covered the method of producing the drug expired in 1979. *Id*., ¶ 74. Not until the late 1990s did the generic companies relevant to this case begin trying to formulate bioequivalent metaxalone products. *Id*., ¶ 79. It appears that no company was able to develop a generic version of Skelaxin that received FDA approval in the preceding two decades.

1. Mutual Becomes the Third ANDA Filer for a 400 mg Generic Metaxalone Tablet in 2003; FDA Has Not Approved Mutual's ANDA

In the late 1990s, the then-owner of Skelaxin (Elan Pharmaceuticals) was selling a 400 mg Skelaxin tablet. *Id.*, ¶ 69. In the early 2000s, three generic competitors filed ANDAs to market and sell a generic 400 mg metaxalone tablet: Eon Labs, Inc. ("Eon") in August 2001; CorePharma LLC ("CorePharma") in April 2002; and Mutual in March 2003. *Id.*, ¶¶ 92, 103. Mutual's ANDA was never approved by the FDA. *See id.*, ¶ 202.

In August 2002, the FDA granted Elan's request for approval to market an 800 mg Skelaxin tablet.[6] *Id.*, ¶ 109. In November 2004 and December 2005, Eon and CorePharma,

[6] A party files a sNDA when it seeks FDA approval to change the strength of a brand-name drug. *Supra*, p. 4.

respectively, amended their ANDAs to seek approval of an 800 mg metaxalone tablet. *Id.*, ¶¶ 166, 203. As Plaintiffs note, generic companies have an incentive to market the same dosage strength as the brand-name product to facilitate substitution by pharmacies of their generic for the brand-name product. *Id.* ¶ 22. Eon later withdrew its 400 mg ANDA. *Id.*, ¶ 166. In 2005, generic drug maker Sandoz, Inc. ("Sandoz") acquired Eon and succeeded to Eon's ANDA for 800 mg metaxalone. *Id.*, ¶ 170. Mutual never sought FDA approval for an 800 mg metaxalone tablet.

In March 2010, the FDA approved Sandoz's 800 mg ANDA. *Id.*, ¶ 234. Sandoz was the first, and to date is the *only*, company to receive FDA approval for a generic metaxalone product. *See id.*

2. Plaintiffs Claim that any Reasonable Lawyer Would Have Known that King's Two Metaxalone Patents Were Invalid by 2004

By January 2004, King owned two method of use patents on Skelaxin. The United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,407,128 ("the '128 Patent") in June 2002 and U.S. Patent No. 6,683,102 ("the '102 Patent") in January 2004. DPP Compl., ¶¶ 98, 107, 129-30. The claims of the '128 and '102 Patents generally covered methods of administering metaxalone wherein patients were informed of the effect of food on the bioavailability of metaxalone (specifically, that more metaxalone gets into the bloodstream when taken with food than when taken on an empty stomach). *Id.*, ¶¶ 98, 130. King listed the '128 and '102 Patents in the Orange Book shortly after each patent was issued. *Id.*, ¶¶ 107, 135.

Plaintiffs rest their antitrust claims on the assertion that any reasonable lawyer would have known the '128 Patent was invalid by June 2002 and the '102 Patent was invalid by January 2004. DPP Compl., ¶¶ 98-101, 113-114, 117, 120, 131.

3. Plaintiffs Contend that King's Patent Lawsuits Were Shams

a. 2003-2004: King Files the *Eon* 400 mg and 800 mg Actions

On January 2, 2003, Elan, King's predecessor, sued Eon in federal court for infringement of the '128 Patent based on Eon's Paragraph IV Certification for its 400 mg metaxalone tablet.[7] *Id.*, ¶¶ 111-13. In December 2004, King sued Eon for infringement of the '102 and '128 Patents based on Eon's Paragraph IV Certification for its 800 mg metaxalone tablet. *Id.*, ¶ 168. The court consolidated the 400 mg and 800 mg actions. *Id*. Plaintiffs allege that these cases were a "sham" from the outset and thus, by January 2003 (for the 400 mg action) and December 2004 (for the 800 mg action), it was obvious to any "reasonable practitioner" that King would lose these cases. *Id*., ¶¶ 113-114, 228.

In January 2009, the court granted Eon summary judgment in the 800 mg case. DPP Compl., ¶ 225. The Federal Circuit affirmed that ruling, although, with respect to some of the asserted claims in the patents, it based its ruling on grounds different from those used by the district court. *See King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010).

Eon later moved for attorney's fees in both the 400 mg and 800 mg cases, strenuously arguing that King's infringement claims were "frivolous." *King Pharm., Inc. v. Eon Labs, Inc*., 2010 WL 3924685, at *12 (E.D.N.Y. Sept. 28, 2010). Of particular relevance here, the New York district court squarely rejected these arguments, stating that

> the eventual success of Eon's position is insufficient to prove that King knew the suit was baseless, especially given the presumption of validity of the suit patents and the fact that the examining

[7] In March 2003, King filed a patent infringement suit against CorePharma over the '128 Patent in response to CorePharma's Paragraph IV Certification for its 400 mg generic metaxalone tablet. DPP Compl., ¶ 116. King and CorePharma settled that case. *Id*., ¶ 203.

> attorney had reviewed several of the same prior art references and still allowed the '102 [P]atent to register.

Id.

b. 2004: King Files the *King v. Mutual* Litigation

In January 2004, Mutual filed a Paragraph IV Certification, claiming that its 400 mg generic metaxalone tablet would not infringe the '102 Patent. DPP Compl., ¶ 137. In response, on March 12, 2004, King filed a patent infringement suit against Mutual in the United States District Court for the Eastern District of Pennsylvania ("the '102 Patent Litigation"). *Id.*, ¶¶ 139-40. Plaintiffs allege this case was also a "sham" from the date it was filed, and thus by March 2004 it was obvious to any "reasonable practitioner" that King would lose the case. *Id*.

In May 2006, the Pennsylvania district court granted a joint motion, placing the case in the Civil Suspense File "[p]ending the outcome of an FDA decision" on a citizen petition submitted by King to the FDA regarding labeling for metaxalone products (discussed below).[8] In January 2008 and July 2010, that court asked the parties for a status report and, on each occasion, Mutual advised the court that the FDA had not decided the pending labeling issues. *See Exhibits* 3 and 4. On August 2, 2010, in response to the July 2010 status report request, Mutual informed the court that the New York district court had invalidated the '102 Patent and that the *Eon* case was on appeal to the Federal Circuit. *See Exhibit* 4. That same day, the Federal Circuit decided the *Eon* appeal. On August 10, 2010, Mutual notified the Pennsylvania

[8] *See* Order dated May 17, 2006, *King Pharm., Inc. v. Mutual Pharm. Co*., Case No. 2:04-cv-01083-LS (E.D. Pa.), attached as *Exhibit* 2. In deciding this motion to dismiss, the Court can take judicial notice of matters of public record, such as a publicly available court order. *In re UnumProvident Corp. Sec. Litig.*, 396 F. Supp. 2d 858, 873-78 (E.D. Tenn. 2005) (Collier, J.) (holding that in deciding a motion to dismiss, "it is well-settled that federal courts may take judicial notice of proceedings of other courts of record").

district court of the Federal Circuit's decision and stated that Mutual did not object to dismissal of the case. *See Exhibit* 5. The court dismissed the case on March 29, 2011.

D. King and a Mutual Subsidiary Assert the '566 Patent against Sandoz

In October 2006, the PTO issued U.S. Patent No. 7,122,566 ("the '566 Patent") to Mutual. The '566 Patent claimed methods of providing a patient with metaxalone and informing the patient about the potential for metaxalone to interact with drugs or foods that inhibit or induce the enzymes that metabolize metaxalone. DPP Compl., ¶ 188. As described further below, King licensed the '566 Patent from Mutual and listed it in the Orange Book. *Id.*, ¶¶ 187-89.

In November 2008, Sandoz amended its ANDA for 800 mg generic metaxalone to include a Paragraph IV Certification that the '566 Patent was invalid or would not be infringed by its proposed product. DPP Compl., ¶ 222. In December 2008, King and a Mutual subsidiary sued to enforce the '566 Patent in the United States District Court for the District of New Jersey (the "*Sandoz* patent litigation"). *Id*., ¶ 223. Again, Plaintiffs allege this case was a "sham" and that, by December 2008, it was obvious to any "reasonable practitioner" that King would lose the case. *Id*., ¶ 224.

The filing of the *Sandoz* patent litigation did ***not*** stay FDA approval of Sandoz's ANDA because Sandoz had filed its ANDA before the PTO issued the '566 Patent. An NDA holder such as King is not entitled to an additional stay against an ANDA filer such as Sandoz even if the NDA holder obtains a new patent. *See supra,* p. 5; *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 691 & n.3 (E.D. Pa. 2004) (noting that, according to legislation passed in 2003, an NDA holder cannot trigger a successive thirty-month stay by listing an additional patent in the Orange Book while an ANDA is pending). The FDA thus approved Sandoz's ANDA in March 2010. Despite Plaintiffs' claims that the *Sandoz* patent litigation was

objectively baseless, it was not decided on summary judgment. Instead, the case was tried in September 2010 to a jury, which rendered a verdict in Sandoz's favor, invalidating the '566 Patent. DPP Compl., ¶ 250.

E. The Alleged Sham Citizen Petitions

1. King's 2004 Citizen Petition

On May 31, 2002, the FDA granted Elan's October 16, 2001 sNDA for Skelaxin, thereby requiring that certain "Food-Effect Labeling" be included in the labels for all metaxalone products. DPP Compl., ¶¶ 97, 106. But, on March 1, 2004, the FDA issued a "Dear Applicant Letter" authorizing ANDA applicants for generic Skelaxin to omit previously-required "Food-Effect Labeling" from their proposed generics. *Id.*, ¶ 142. On March 18, 2004, King filed a citizen petition with the FDA requesting that it reconsider and rescind the Dear Applicant Letter and require all ANDA applicants for generic Skelaxin to include the Food-Effect Labeling on the generic label. *Id.*, ¶¶ 147-48. The Food-Effect Labeling implicated the '128 and '102 Patents. *Id.*, ¶¶ 98, 102, 107, 129-130. Mutual initially opposed King's citizen petition in submissions to the FDA, but later supported King's petition in filings with the FDA. *Id.*, ¶¶ 155-56, 163-64, 182. On February 7, 2007, King filed a supplemental petition asking the FDA to prohibit ANDA applicants from carving out the food effect information from the label for generic metaxalone. *Id.*, ¶ 206. Mutual supported this supplemental petition in a filing with the FDA. *Id.*, ¶ 208. The FDA has never rejected King's 2004 citizen petition or 2007 supplemental petition.[9]

[9] Plaintiffs do not allege that the FDA has taken any action on these citizen petitions, and thus the Court can conclude that the FDA has not taken any action. *See Scheid v. Fanny Farmer Candy Shops, Inc.*, 859 F.2d 434, 436-37 (6th Cir. 1988).

2. Mutual's 2007 and 2008 Citizen Petitions

In July 2007 and January 2008, Mutual submitted two separate citizen petitions to the FDA requesting that it adopt labeling rules that would require generic competitors to include labeling information that would implicate the '566 Patent. *Id.*, ¶¶ 212-13. Those citizen petitions were denied. *Id*., ¶ 219.

3. Mutual's 2009 Citizen Petition

On May 13, 2009, Mutual filed a citizen petition asking the FDA to require King to update the Skelaxin label to reflect that the 800 mg Skelaxin tablet is a delayed-release dosage form. *Id.*, ¶ 231. The FDA has never rejected this citizen petition. *See supra*, n.9.

F. The 2005 License Agreement between King and Mutual

On December 6, 2005, King and Mutual entered into the 2005 License Agreement. DPP Compl., ¶ 176. On May 3, 2006, the 2005 License Agreement became publicly available when King attached it to its Form 10-K filed with the United States Securities and Exchange Commission ("SEC").[10]

Plaintiffs contend that the 2005 License Agreement is anticompetitive because they say it provides that (i) Mutual will not enter the market with a generic metaxalone product; and (ii) King and Mutual will delay or obstruct generic competition. DPP Compl., ¶ 176. The 2005

[10] On a motion to dismiss, the Court can take judicial notice of the fact that the 2005 License Agreement was attached to King's SEC filing. *See Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1275-81 (11th Cir. 1999) (approving practice of judicially noticing public disclosures filed with SEC); *In re UnumProvident*, 396 F. Supp. 2d at 875 (Collier, J.) (citing *Bryant* and taking judicial notice of assorted SEC filings).

License Agreement says nothing of the sort. Rather, Plaintiffs allegations are directly contradicted by the terms of the Agreement and thus the Court should disregard them.[11]

In truth, the 2005 License Agreement granted King a "co-exclusive (with Mutual) license" to use Mutual's intellectual property to "make, use, offer for sale, sell and import" King's own existing and future products containing metaxalone. *Exhibit* 6, §§ 2.1(a), 2.4. Thus, Mutual retained all of its rights to use the intellectual property it licensed to King, and Mutual could use the licensed intellectual property to make, use, offer for sale, sell, or import Mutual's own existing and future products containing metaxalone. *Id.* The plain language of the 2005 License Agreement does not prevent Mutual from entering the generic Skelaxin market or otherwise delay or obstruct generic competition, and Plaintiffs have not alleged any other secret, unwritten agreement so providing.

The intellectual property licensed by Mutual to King in the 2005 License Agreement includes the patent application that ultimately issued as the '566 Patent. DPP Compl., ¶ 189. Thus, the 2005 License Agreement ultimately granted King a license to the '566 Patent.

STANDARD OF REVIEW

To withstand a motion to dismiss, a complaint "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "[C]ourts may no longer accept conclusory legal allegations that do not include specific facts necessary to establish the cause of action." *New*

[11] Where allegations are contradicted by documents referenced in the complaint, the document controls and the court need not accept as true the allegations of the complaint. *E.g.*, *Williams v. CitiMortgage, Inc.*, 2011 WL 1303257, at *4 (S.D. Ohio Mar. 31, 2011) (ruling that, on a motion to dismiss, the district court is not "constrained" to accept as true allegations that are contradicted by "documents upon which [plaintiff's] pleadings rely"), *aff'd per curiam*, 2012 WL 3834776, at *4 (6th Cir. Sept. 4, 2012) (unpublished).

Albany Tractor, Inc. v. Louisville Tractor, Inc., 650 F.3d 1046, 1050 (6th Cir. 2011); *see also Drake v. Citimortgage, Inc.*, 2011 WL 1396774, at *2 (E.D. Tenn. Apr. 13, 2011) (Collier, C.J.) ("[T]he court is not bound to accept as true a legal conclusion couched as a factual allegation").

Claims are subject to dismissal where the factual allegations do not state a "plausible" claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 558-59 (2009); *Twombly*, 550 U.S. at 554-67, 570. It is not enough to allege facts from which it can be inferred that a defendant *may* have violated the law; rather, the complaint must nudge the plaintiff's claims "across the line from conceivable to plausible." *See, e.g.*, *Twombly*, 550 U.S. at 564-67, 570 (holding that specific factual allegations of parallel business conduct alongside conclusory assertions of a conspiracy failed to state an antitrust claim). In evaluating plausibility, the court should consider "context" and "draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* at 678. Plaintiffs must instead allege facts that are *inconsistent* with a defendant's *lack* of liability. *Id.* Courts applying these principles consistently dismiss antitrust claims that fail to provide enough factual detail to state a plausible claim for relief.[12]

"Sham" claims require even more particularized allegations. "When pleading the sham exception to the *Noerr-Pennington* doctrine, courts have required more specific allegations"

[12] *See, e.g.*, *New Albany*, 650 F.3d at 1050 (affirming dismissal of antitrust action where plaintiff retailer failed to sufficiently allege that defendant manufacturer actually controlled distributor despite affidavit from retailer's president); *Terry v. Tyson Farms, Inc.*, 604 F.3d 272 (6th Cir. 2010) (affirming dismissal of antitrust action where plaintiff's allegations of how defendant's conduct had injured plaintiff's business were insufficient to establish anticompetitive effect); *In re Travel Agent Comm'n Antitrust Litig.*, 583 F.3d 896 (6th Cir. 2009) (affirming dismissal of antitrust action where allegations were insufficient to state a conspiracy claim); *CBC Co. v. Equifax, Inc.*, 561 F.3d 569 (6th Cir. 2009) (affirming dismissal of antitrust action).

because such a case "implicates conduct which is *prima facie* protected by the [F]irst [A]mendment." *Letica Corp. v. Sweetheart Cup Co.*, 790 F. Supp. 702, 706 (E.D. Mich. 1992) (holding that plaintiffs "failed to plead with the required specificity that defendant's activities were a mere sham").[13] Plaintiffs alleging sham claims should be required to meet Rule 9(b)'s heightened pleading standard. *See, e.g.*, *Kottle v. N.W. Kidney Ctrs.*, 146 F.3d 1056, 1063 (9th Cir. 1998).

But, Plaintiffs have not met their pleading burdens under any standard because they do no more than advance conclusory allegations in support of their claims. Plaintiffs' complaints, *each* weighing in at over 300 numbered paragraphs and about 100 pages, do not suffer from a shortage of words. But what they lack are the specific *facts* supporting their claims that courts require in cases like this.

ARGUMENT

I. PLAINTIFFS' FEDERAL JOINT CONDUCT CLAIMS FAIL TO ALLEGE COGNIZABLE ANTICOMPETITIVE CONDUCT

Claims II and III of the DPPs Complaint; the First, Third, and Fourth Claims for Relief in the EPPs' Complaint; and Claims II and III in the *Walgreen* Complaint are brought against both King and Mutual, alleging joint conduct by them. DPP Compl., ¶¶ 307-22; EPP Compl., ¶¶ 320-45; Walgreen Compl., ¶¶ 245-58. As detailed below, Plaintiffs challenge as anticompetitive joint conduct: (i) the assertion of the '566 Patent against Sandoz, (ii) a joint request to stay the '102 Patent litigation, (iii) various FDA citizen petitions, (iv) and Mutual's alleged agreement not to

[13] *See also Dish Network, LLC v. Fun Dish Inc.*, 2010 WL 5230861, at *11 (N.D. Ohio July 30, 2010) ("When pleading the sham exception to the *Noerr-Pennington* Doctrine, courts have required more specific allegations."), *adopted as modified*, 2010 WL 5230860 (N.D. Ohio Dec. 16, 2010); *Rockbit Indus. U.S.A., Inc. v. Baker Hughes, Inc.*, 802 F. Supp. 1544, 1552 (S.D. Tex. 1991) ("In light of the fundamental first amendment values that the *Noerr-Pennington* doctrine is designed to protect, a complaint should contain specific allegations demonstrating that the *Noerr-Pennington* protections do not apply.").

enter the market with a generic product. The Court should dismiss all of these joint conduct claims because Plaintiffs fail to plausibly allege that any of the challenged conduct caused them actual injury and because almost all of the challenged conduct is protected by the First Amendment.

A. The *Sandoz* Patent Litigation and the '102 Patent Case Were Not Anticompetitive

Plaintiffs' joint conduct claims focus on two patent litigations but, as shown below, neither could have caused Plaintiffs any harm. Moreover, the First Amendment and the *Noerr-Pennington* doctrine broadly immunize litigation conduct from antitrust liability. *See United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."); *Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 137 (1961).

To strip a party of those First Amendment privileges for litigation conduct, a plaintiff must plead, and ultimately prove, that the challenged litigation was a "sham," meaning both (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and (2) brought with a "subjective motivation" to "'interfere *directly* with the business relationships of a competitor'" rather than to prevail in the litigation. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993) [hereinafter, "*PRE*"].

The Supreme Court has made this standard very difficult to meet: only a "rare plaintiff" can prove a sham. *Id.* at 75 (Stevens, J., concurring in the judgment). "Access to the courts is far too precious a right for us to infer wrongdoing from nothing more than using the judicial process to seek a competitive advantage in a doubtful case." *Id.* at 69-70; *see also White v. Lee*, 227 F.3d 1214, 1232 (9th Cir. 2000) (to conclude that "litigation . . . is objectively baseless" is "a result [a court] would reach only with great reluctance"). Plaintiffs' claims of sham patent

litigation face an even higher burden -- clear and convincing proof. *Golan v. Pingel Enter., Inc.*, 310 F.3d 1360, 1371 (Fed. Cir. 2002). That is because "[t]he law recognizes a presumption that the assertion of a duly granted patent is made in good faith." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998) (en banc).

1. The *Sandoz* Patent Litigation Was Not Anticompetitive

a. The *Sandoz* Patent Litigation Could Not Have Injured Plaintiffs

In a silence that speaks volumes, Plaintiffs' complaints do not explain how the *Sandoz* patent litigation could have delayed generic entry or otherwise injured Plaintiffs. As noted above, that case did not result in a thirty-month stay of FDA approval of Sandoz's generic application. *Supra*, pp. 13-14. Defendants know of no case in which a court has found potential injury where, as here, downstream purchasers claimed delayed generic entry based on a patent case that did not create a thirty-month stay of approval. Without a stay of FDA approval, there is no basis on which to infer that an allegedly "sham" patent case could delay generic approval or market entry. Indeed, Sandoz obtained FDA approval and entered the market during the pendency of the *Sandoz* patent litigation, negating any suggestion that it prevented Sandoz from going to market. DPP Compl., ¶¶ 237-39. That should be the end of Plaintiffs' accusations regarding the *Sandoz* patent litigation.

b. Plaintiffs' Conclusory Allegations of "Sham" Litigation Are Insufficient

Separately, Plaintiffs' allegations of sham are entirely conclusory or implausible. For example, Plaintiffs have not alleged facts sufficient to plausibly suggest that the *Sandoz* patent litigation was brought in subjective bad faith, *i.e.*, that King and Mutual filed the case knowing they had no chance of prevailing but instead sought to use the lawsuit itself to delay Sandoz. With respect to subjective bad faith, the Walgreen Complaint simply restates the legal standard,

alleging that the litigation "was commenced solely to delay generic competition through the filing and maintenance of the lawsuit rather than by obtaining a favorable outcome." Walgreen Compl., ¶ 182.

But, Plaintiffs have to plead *facts* that nudge the allegations "across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. Thus, they cannot ignore the need to allege facts demonstrating King's and Mutual's subjective bad faith. Case after case requires Plaintiffs to plead "affirmative" facts demonstrating bad faith to prevail on an allegation of "sham" patent assertion. *E.g.*, *Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH*, 524 F.3d 1254, 1260, 1264 (Fed. Cir. 2008); 310 F.3d at 1360, 1371. This is because patent litigation is legally presumed to be brought in good faith:

> A plaintiff [alleging sham litigation] has an especially difficult burden in the patent enforcement context because "the law recognizes a presumption that the assertion of a duly granted patent is made in good faith; this presumption is overcome only by affirmative evidence of bad faith."

In re Terazosin Hydrochloride Antitrust Litig., 335 F. Supp. 2d 1336, 1365 (S.D. Fla. 2004) (quoting *Bard*, 157 F.3d at 1369). Plaintiffs' failure to plead facts showing bad faith is fatal to the claims relating to the *Sandoz* patent litigation.

Moreover, the suggestion that the *Sandoz* patent litigation was brought in subjective bad faith is simply implausible. Under *PRE*, bad faith does not mean simply intending to harm a competitor or to delay a competing product through litigation: "the intention to harm a competitor . . . is the very matter protected under *Noerr-Pennington*." *Potters Med. Ctr. v. City Hosp. Ass'n*, 800 F.2d 568, 579 (6th Cir. 1986). Rather, to be a sham, a case must be brought not to win but rather to harm a competitor through the mere filing of the lawsuit: "[T]he requisite motive for the sham exception is the intent to harm one's competitors, not by the result of the [petitioning] but by the simple fact of the institution of [a petition]." *Id.* A suit brought in bad

faith is one that is brought with "no expectation of achieving" victory. *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991) (explaining that a suit brought in bad faith is "'not genuinely aimed at procuring favorable government action' at all").

It is implausible that King and Mutual brought the *Sandoz* patent litigation to delay Sandoz through the *process* of litigation rather than the outcome of the litigation because, as explained above, the case could not result in a stay of FDA approval. *See supra*, pp. 13-14. Thus, the *Sandoz* patent litigation could only benefit King and Mutual if they prevailed. Indeed, Sandoz gained approval and entered the market during the pendency of the *Sandoz* patent litigation. *See* DPP Compl., ¶¶ 234-239. Plaintiffs have thus failed to identify any reason for King and Mutual to bring the *Sandoz* patent litigation if they thought they had no chance of success. In evaluating the plausibility of allegations, the Court should "draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. Plaintiffs' allegations defy common sense.

2. Defendants' Request to Stay the '102 Patent Litigation Was Not Anticompetitive

Plaintiffs also complain that it was improper for King and Mutual jointly to request a stay of the '102 Patent case in May 2006 because of Mutual's supposed "secret" agreement not to market a generic metaxalone product. DPP Compl., ¶¶ 192-199. Had the court not granted the stay, Plaintiffs theorize, the King '102 Patent would have been invalidated in late 2006. Again, this claim makes no sense.

First, Defendants' request for a stay of the litigation, like any petition to the courts, is immune from antitrust liability under *Noerr-Pennington*. Plaintiffs have not even tried to assert that the request to stay was somehow objectively baseless and made in subjective bad faith.

Second, had King and Mutual disclosed their alleged secret agreement, the court would have dismissed the '102 case for lack of a case or controversy. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997). Plaintiffs themselves all but admit this. DPP Compl., ¶ 194 (noting that disclosing supposed "secret" settlement to '102 court would likely have led to case being "dismissed for lack of a justiciable controversy"). Once the case was dismissed, it obviously could not have resulted in the invalidation of the '102 Patent.

Third, even if the case had been allegedly settled and not been stayed, Plaintiffs cannot assert a viable antitrust theory based on the idea that the '102 Patent would then have been invalidated. Courts have rejected the idea that claims can be premised on "proving" how a hypothetical trial or proceeding would have come out. *See In re Ciprofloxacin Hydrochloride Antitrust Litig. ("Cipro")*, 261 F. Supp. 2d 188, 200-01 (E.D.N.Y. 2003) (noting that courts should not entertain claims that speculate about the outcome of litigation); *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case."). Nor does the fact that another court later found the '102 Patent invalid mean that the court hearing the King Mutual case would have yielded the same result. Courts often reach conflicting outcomes, especially in patent cases. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 193-95 (2d Cir. 2006) (explaining the different decisions reached by different district courts regarding the validity of AstraZeneca's patent covering the drug tamoxifen citrate); *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J., by designation) ("No one can be *certain* that he will prevail in a patent suit."). No one can know how the original '102 case would have come out and, for that reason, such speculation in Plaintiffs' complaint does not satisfy *Twombly*.

Fourth, even if Plaintiffs could somehow establish that, but for the stay, the '102 Patent would have been invalidated in late 2006, Plaintiffs are unable to explain how that would have resulted in earlier generic entry. Although King later asserted the '102 Patent against Sandoz's 800 mg product in December 2004, there is no suggestion in the complaints that the '102 Patent delayed Sandoz's market entry. DPP Compl., ¶¶ 168-69. Indeed, the thirty-month stay of FDA approval associated with the '102 Patent expired in mid-2007, yet Sandoz did not enter the market until April 2010. (The '102 Patent was eventually declared invalid in January 2009.) Obviously, the '102 Patent was not what prevented Sandoz's market entry and nothing in the complaints establishes otherwise. Even if the '102 Patent had been invalidated in late 2006, Plaintiffs make no allegation explaining how Sandoz would then have suddenly been able to come to market.

B. Plaintiffs Have No Viable Antitrust Claim Based on King's and Mutual's Citizen Petitions to the FDA

Plaintiffs also challenge citizen petitions filed by King and Mutual with the FDA after the 2005 License Agreement. Plaintiffs challenge the citizen petitions as "sham" joint conduct based on the assertion that Mutual agreed in the 2005 License Agreement to help King "delay other would-be generic competitors from gaining FDA approval." DPP Compl., ¶¶ 176-78. The 2005 License Agreement says no such thing. *See Exhibit* 6. But, even if the citizen petitions had been the result of joint conduct, Plaintiffs still would have no viable claim.

1. Plaintiffs' Citizen Petition Challenges Are Blocked by FDCA Section 505(q) or the Statute of Limitations

Since September 27, 2007, citizen petitions have been subject to Section 505(q) of the FDCA. *See* DPP Compl., ¶ 59 n.23. Section 505(q) provides that the FDA "shall not delay approval of a pending [ANDA]" based on the pendency of a citizen petition unless the FDA expressly finds that the "delay is necessary to protect public health." 21 U.S.C. § 355(q)(1)(A).

The FDA made no such "public health" finding here, so no citizen petition could have delayed any metaxalone ANDA since September 27, 2007.

As for petitions filed before September 2007, they were well outside the statute of limitations, as explained in Section IV below.

2. There Is No "Sham" Exception to the First Amendment Immunity for Non-Adjudicative Proceedings Like FDA Citizen Petitions

Plaintiffs' claims regarding the citizen petitions are also barred by Defendants' First Amendment right to petition an executive agency. *See Cal. Motor Transp. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). Plaintiffs seek to avoid the First Amendment by alleging the citizen petitions were all "shams" under *PRE*. 508 U.S. 49, 60-61 (1993) (First Amendment protects petitioning before an adjudicative body unless petition is (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and is (2) brought with a "subjective motivation" to "interfere directly with the business relationships of a competitor" rather than to prevail in the litigation). But the sham exception is inapplicable here.

a. The "Sham" Exception Applies Only to Adjudications

Every court of appeals to address the issue, including the Seventh, Ninth, and Eleventh Circuits, has held that the *PRE* sham exception applies only to adjudicatory proceedings. *See St. Joseph's Hosp., Inc. v. Hosp. Corp. of Am.*, 795 F.2d 948, 955 (11th Cir. 1986) (sham exception applied only where governmental agency "is passing on specific certificate applications" and thus "acting judicially"); *Mercatus Group., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 843-49 (7th Cir. 2011) (sham exception to *Noerr-Pennington* immunity "does not apply at all outside of adjudicative proceedings"); *Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1061 (9th Cir. 1998) ("It is obvious that [the ways] in which litigation might be a sham do not necessarily extend beyond the litigation context."); *see also Livingston Downs Racing Ass'n v. Jefferson Downs Corp.*, 192

F. Supp. 2d 519, 534 n.14 (M.D. La. 2001) ("[P]etitions which do not involve the individualized application of established principles cannot be reviewed for objective merit, as required under [*PRE*]."). The leading antitrust treatise reaches the same conclusion. 1 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 204(b) (3d ed. 2006). The Sixth Circuit has also explained that the sham doctrine applies to "'unethical conduct in the *adjudicatory* process.'" *Potters*, 800 F.2d at 578 (emphasis added). *Potters* applied the sham exception to a Certificate of Need proceeding, which has been found to be adjudicatory in nature. *See, e.g.*, *Kottle*, 146 F.3d at 1062-63; *St. Joseph's*, 795 F.2d at 955.

There are many reasons for limiting the sham exception to adjudicatory proceedings. Most obviously, the "objective baselessness" standard cannot be applied where an agency exercises its discretion rather than uses "objective" legal standards for decision-making. *See Manistee Town Ctr. v. City of Glendale*, 227 F.3d 1090, 1094 (9th Cir. 2000) ("There are no enforceable standards by which either of the two prongs of the *Professional Real Estate* test can be applied. The exception simply does not fit."); *see also* 1 AREEDA & HOVENKAMP, *supra*, ¶ 204(b) (explaining that, in non-adjudicative context, "one could not develop an 'objective test' whether the legislation or rule sought was manifestly unreasonable, for the First Amendment petitioning right is not limited to reasonable requests").

There are cases that have applied the sham exception to what might be categorized as non-adjudicatory proceedings, but none of those cases actually examined the question of whether such an application was proper. *See United States v. Mitchell*, 271 U.S. 9, 14 (1926) ("It is not to be though that a question not raised by counsel or discussed in the opinion of the court has been decided merely because it existed in the record and might have been raised and considered.").

No court of appeals that has considered the issues has rejected the concept that the sham doctrine applies only to adjudicatory proceedings. In fact, Defendants could find no more than two district courts that have considered and rejected the limitation on the sham doctrine recognized unanimously by the appellate courts cited above. *See In re Prograf Antitrust Litig.*, 2012 WL 293850, at *5-6 (D. Mass. Feb. 1, 2012); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011). These two district court decisions were based on the fear that by limiting the sham exception to adjudicatory proceedings, "any act of advocacy before a legislative or quasi-legislative body would be shrouded in carte blanche immunity." *Prograf*, 2012 WL 293850, at *5. Defendants respectfully suggest that these two opinions are incorrect. Even if they were not, however, they would be inapposite: the two district court cases involved the question of whether the First Amendment immunized petitioning involving *fraud*, not whether it immunized petitioning involving accurate (but allegedly irrelevant) information to an agency.

b. These FDA Citizen Petitions Were Not Adjudicatory

Thus, Plaintiffs cannot rely on a "sham" exception to First Amendment immunity unless the FDA citizen petition process is adjudicatory in nature, and it is clear that citizen petitions are not adjudicatory. "Denial of a citizen petition is a final agency action subject to judicial review, *but it is not an adjudication*" under the Administrative Procedure Act. *Henley v. FDA*, 873 F. Supp. 776, 781 (E.D.N.Y. 1995) (emphasis added), *aff'd*, 77 F.3d 616 (2d Cir. 1996).

The FDA citizen petition process has little in common with a traditional adjudicative proceeding. Testimony is not typically given under oath or penalty of perjury. There are no rules of evidence or fixed rules of procedure. There are no rules of standing and no concept of parties. Any interested person may seek to lobby the FDA, even on an *ex parte* basis. Indeed, *ex parte* meetings are *encouraged*. 21 C.F.R. § 10.65(c) ("[e]very person outside the Federal

Government may request a private meeting with a representative of FDA in agency offices to discuss a matter," and the FDA must "make reasonable efforts to accommodate such requests"). There is no requirement that these *ex parte* communications even be transcribed or recorded, so persons opposing citizen petitions have every right to forgo written submissions in favor of unrecorded, *ex parte* lobbying efforts. *Id.* § 10.65(e). Even for written submissions, there is no requirement that one person's submissions be shared with other interested persons. *See, e.g.*, DPP Compl., ¶¶ 160, 163 (discussing Mutual's attempts to obtain data on which King had relied on in submitting its citizen petitions). Thus, neither interested persons nor the courts can necessarily determine everything that the FDA considered in a decision-making process.

Beyond the fact that the citizen petition process has no procedural similarities to adjudication, it also lacks the substantive limitations of adjudication. Unlike a complaint, a citizen petition is not limited in the issues it may raise or the relief it can request. A citizen petition can request the FDA to take "any administrative action" for any reason. 21 C.F.R. § 10.25(a). A citizen petition can focus on a specific drug application, a rule to be applied to a group of applications (like here), or on broader policy issues. The regulations also put few limits on what information or policies the FDA is permitted to consider in its decision-making process, unlike an adjudicatory tribunal, which is limited to an evidentiary record. *See, e.g., id.* § 320.24 (listing the various types of evidence that may be submitted to demonstrate bioavailability and bioequivalence). There are no substantive standards controlling the FDA's decision on the relevant King and Mutual citizen petitions beyond "safety and efficacy." *See, e.g., id.* § 314.127(a)(7) (standard for labeling change carve-out is whether generic would be "less safe or effective" than brand). But, "safety" and "efficacy" are no more and no less than the entire and "essential purpose" of the Food and Drug laws. *See Food & Drug Admin. v. Brown &*

Williamson Tobacco Corp., 529 U.S. 120, 133-34 (2000). In other words, the FDA's decisions on the citizen petitions here were necessarily guided only by the agency's scientific expertise and its perception of what actions were necessary to fulfill its broad core mission. Given the FDA's expertise and broad substantive discretion, the FDA's substantive judgment about what is safe and effective cannot be second-guessed by courts, but is subject to only "a very narrow and deferential scope of review." *Henley*, 873 F. Supp. at 781 ("[T]he Court is mindful that when it reviews agency action that is based upon scientific inquiry and technical expertise, a high degree of deference is appropriate").

Since the FDA would have been free to consider the information that King and Mutual provided and change course based on this information, this Court cannot say accurately that King and Mutual's arguments were "objectively baseless." How can a court say that an argument made to the FDA is "objectively baseless" when the FDA would have been free to consider the underlying data relevant to "safety and efficacy"? "[E]xecutive entities are treated like judicial entities [for *PRE* purposes] only to the extent that their actions are guided by enforceable standards subject to review." *Kottle*, 146 F.3d at 1061.

Finally, in close cases -- where it is unclear whether a proceeding is adjudicative -- courts should err on the side of preserving First Amendment immunity. *See Mercatus*, 641 F.3d at 846-47. This is because "*Noerr-Pennington* was crafted to protect the freedom to petition guaranteed under the First Amendment," and the risk of chilling protected speech "will be particularly pronounced when, as is the case with the antitrust laws, [] allegedly fraudulent statements may be punishable by treble damages." *Id.* It is easy to imagine the dangerous chilling effect if King's and Mutual's efforts to require additional safety data on generic labels could subject them to treble antitrust damages, regardless of which side the FDA agreed with.

Because the citizen petition process is not adjudicative, the Court should dismiss all of Plaintiffs' challenges to King's and Mutual's citizen petitions.

C. Mutual's Failure to Market a Metaxalone Product Cannot Be Attributed to the 2005 License Agreement

Finally, Plaintiffs allege that Mutual agreed in the 2005 License Agreement "not to enter the market with any generic metaxalone product." DPP Compl., ¶¶ 5, 176. But, nowhere does the 2005 License Agreement say anything remotely like that. *See Exhibit* 6. To the contrary, the license expressly preserves Mutual's right to use its intellectual property to bring its own product to market. *See id.* § 4.2. Plaintiffs insinuate that there might have been some other agreement by Mutual not to enter the market, but allege no specifics. Plaintiffs point to the payments from King to Mutual as a *quid pro quo* for Mutual's other alleged agreement, but Mutual was entitled to the payments specified in the 2005 License Agreement regardless of whether it entered the market. *See Exhibit* 6 art. 4 (granting King a *non-exclusive* license to Mutual's intellectual property).

More fundamentally, Plaintiffs fail to address the basic fact that Mutual never obtained FDA approval for a metaxalone product that it could market. Plaintiffs do not allege that Mutual ever had a viable 800 mg product under development, and Mutual's ANDA for a 400 mg product never received even tentative FDA approval, despite having been filed in March 2003. *Supra*, pp. 9-10. Plaintiffs have thus not alleged any cognizable injury resulting from Mutual's imagined agreement to stay out of the market.

Courts from at least three circuits considering alleged agreements by generics not to market a product have held that downstream purchasers cannot show injury unless the relevant generic company received tentative FDA approval that would demonstrate that the company at least had a viable, approvable product. *See, e.g.*, *Terazosin*, 335 F. Supp. 2d at 1368 (noting that

"without tentative FDA approval, a generic manufacturer cannot enter the marketplace, and thus there is no antitrust injury" because "[i]n a regulated industry, the failure to get needed regulatory approval may 'cut[] the causal chain'"); *Cipro*, 261 F. Supp. 2d at 240-41 (FDA grant of tentative approval needed to indicate that generic manufacturer "was at least a potential competitor"); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 24 (D. Mass. 2000) (requiring tentative FDA approval to demonstrate injury in fact).

The few district court cases in the Third Circuit that have disagreed, holding that plaintiffs could plead antitrust claims based on the possibility that the grant of tentative approval had been improperly delayed, are entirely distinguishable from this case.[14] Critically, however, almost all of these cases involved generics that ultimately received FDA approval, albeit after the alleged anticompetitive conduct had ceased. The eventual FDA approval demonstrated that the generics had at least developed an approvable product. These cases are therefore inapposite because Plaintiffs have not pled, and cannot plead, that Mutual ever had a product that the FDA approved. In any case, Defendants respectfully suggest that these cases are wrongly decided. Without tentative approval from the FDA, Plaintiffs must prove, and the Court would have to rule, that the FDA would have, in the exercise of its considerable discretion, granted Mutual's ANDA application -- an impossible task built on pure speculation. Claims cannot be predicated on theories that require a plaintiff to prove in advance how a court or agency would decide a specific issue. *Cf. Cipro*, 261 F. Supp. 2d at 200-01 (noting that courts should not entertain claims that speculate about the outcome of litigation); *Whitmore*, 495 U.S. at 159-60 ("It is just

[14] *See, e.g.*, *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, 2010 WL 1485328, at *7 (D. Del. Apr. 13, 2010); *In re Neurontin Antitrust Litig.*, 2009 WL 2751029 (D.N.J. 2009); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003).

not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.").

FDA approval of a generic drug is not a foregone conclusion, as the facts of this case amply demonstrate. As Plaintiffs themselves note, more than three *decades* passed before any generic company even tried to obtain approval for a generic metaxalone product. DPP Compl., ¶¶ 69, 79. According to Plaintiffs, Mutual had such great difficulty developing its 400 mg product that it was not in a position even to *apply* for FDA approval until 2003. *Id*., ¶¶ 80, 118 And, there is no suggestion in the complaints that Mutual was able to develop an 800 mg product, even though King received approval for an 800 mg product in 2002 and even though thereafter any generic would want to market an AB-rated 800 mg generic product. *Supra* pp. 9-10.

II. THE IPPs FAIL TO STATE A CLAIM FOR A VIOLATION OF THE TENNESSEE TRADE PRACTICES ACT

Claim I of the IPPs' Complaint asserts a claim under the Tennessee Trade Practices Act ("TTPA"), Tenn. Code Ann. §§ 47-25-101 *et seq*. The Court should dismiss this claim because the IPPs fail to allege facts showing that they were harmed by conduct of King and Mutual which also had "substantial effects" on Tennessee trade or commerce. To the contrary, the IPPs expressly exclude from their asserted class all Tennessee retailers. The IPP claims concern only retailers and metaxalone sales outside of Tennessee.

The TTPA, however, is limited to claims involving "substantial effects" on *intrastate* Tennessee trade or commerce. *See Freeman Indus., LLC v. Eastman Chem. Co.*, 172 S.W.3d 512, 523 (Tenn. 2005). In *Freeman*, Tennessee's highest court affirmed the lower court's grant of a motion to dismiss TTPA claims where the defendant allegedly engaged in anticompetitive

conduct in Tennessee that resulted in a nationwide price-fixing scheme that was not alleged to have had a "substantial effect" on *intrastate* Tennessee commerce. *Id*. at 524.

Following *Freeman*, many other courts have rejected TTPA claims challenging alleged nationwide antitrust schemes where the plaintiff has not alleged specific "substantial effects" on *intrastate* Tennessee trade or commerce.[15] Indeed, even if there were Tennessee plaintiffs, the Tennessee Supreme Court held that it is insufficient to simply allege that the Tennessee plaintiffs paid a higher price: "Freeman fails to establish how the defendants' anticompetitive conduct affected Tennessee commerce to a substantial degree even though the conduct resulted in Freeman paying higher prices to retailers for items containing sorbates." *Id*.

Here, as noted, the IPPs' complaint expressly excludes any Tennessee plaintiffs and is thus necessarily completely devoid of allegations regarding effects on *intrastate* Tennessee trade or commerce.[16] IPP Compl., ¶¶ 286, 301. The only "effects" that the IPPs plead are their own

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[15] *See In re Magnesium Oxide Antitrust Litig.*, CIV. 10-5943, 2011 WL 5008090, at *8 n.10 (D.N.J. Oct. 20, 2011) (dismissing TTPA claim on a Rule 12(b)(6) motion because plaintiffs' allegations that "'prices for MgO and MgO Products were raised, fixed, maintained, and stabilized at artificially high levels throughout the states,' and that 'Defendants' illegal conduct had a substantial effect on commerce in the above states'" were conclusory and, therefore, insufficient); *In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 416 (E.D. Pa. 2009) (dismissing TTPA claim on a Rule 12(b)(6) motion where plaintiffs "failed to allege that the anticompetitive conduct had a substantial effect on Tennessee commerce"); *see also Medison Am., Inc. v. Preferred Med. Sys., LLC*, 357 F. App'x 656, 662-63 (6th Cir. 2009) (unpublished) (holding that rejection of TTPA claim on defendants' motion for summary judgment was proper because plaintiff-seller of ultrasound equipment failed to show substantial effect on trade or commerce or any attempt by its competitor to monopolize a particular market; "In Tennessee, a plaintiff must prove that the defendant entered into an anticompetitive agreement that 'affects Tennessee trade or commerce to a substantial degree.'").

[16] Although the IPPs' Complaint includes a section titled "Substantial Effects on Tennessee Trade on Commerce," those allegations all relate to Defendants' *conduct* in Tennessee, rather than the *effects* of that conduct on Tennessee's trade or commerce. *See* IPP Compl., ¶¶ 283-84. Such allegations are plainly insufficient to plead a TTPA claim. *See Freeman*, 172 S.W.3d at 524 ("The focus under the substantial effects standard . . . is not on the anticompetitive conduct itself but on the *effects* of the conduct on Tennessee commerce. While

purported injuries, alleged overpayments for Skelaxin outside of Tennessee. *See*, *e.g.*, IPP Compl., ¶¶ 264-69, 281-82. This is clearly insufficient as the basis for a TTPA claim. *Medison*, 357 F. App'x at 662-63 ("[T]he only effects that [plaintiff] cites here are its own alleged injuries, which do not amount to a 'substantial' effect on Tennessee trade or commerce as a whole."). Because the IPPs operate their businesses *outside* Tennessee and do not purport to serve Tennessee consumers, IPP Compl., ¶ 286, they could not possibly have suffered harm that had a substantial effect on Tennessee trade and commerce. The IPPs cannot maintain their claims under the TTPA.

The Court should dismiss Claim I of the IPPs' Complaint.

III. THE COURT SHOULD DISMISS THE UNJUST ENRICHMENT CLAIMS

Claim VIII of the IPP Complaint alleges nationwide unjust enrichment claims (minus Tennessee). IPP Compl., ¶¶ 353-56. The Fourth Claim for Relief in the BCBS Complaint asserts an unjust enrichment claim without identifying the law of any state. BCBS Compl., ¶¶ 163-75. The Sixth Claim for Relief in the EPPs' Complaint asserts unjust enrichment claims under the laws of twenty-one states.[17] EPP Compl., ¶¶ 346-358. The Court should dismiss all of these unjust enrichment claims.

A. The IPPs and *BCBS* Plaintiffs Fail to State a Claim for Unjust Enrichment Because They Fail to Specify the Unjust Enrichment Laws Applicable to Their Claims

There is no such thing as a federal general common law applicable to all states and jurisdictions. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). As a result, a plaintiff

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Freeman alleged that Eastman took orders and implemented sales to customers at the new prices from Tennessee, we do not believe that this bare allegation without more is sufficient . . . .").

[17] The DPPs and the *Walgreen* Plaintiffs do not assert unjust enrichment claims.

cannot plead an unjust enrichment claim untethered to the law of any particular state. For example, in *In re Wellbutrin XL Antitrust Litigation*, 260 F.R.D. 143 (E.D. Pa. 2009), the court dismissed a similar unjust enrichment claim. *Id.* at 167. Observing that "the amended complaint . . . [did] not reference any basis in law on which a claim for unjust enrichment might proceed" and that plaintiffs "failed to link their claim to the law of any particular state," the court noted that "cobbling together the elements of a claim of unjust enrichment from the laws of the fifty states is no different from applying federal common law" and held that plaintiffs failed to state an unjust enrichment claim. *Id.* Courts have repeatedly dismissed similarly undifferentiated unjust enrichment claims.[18]

Here, the IPPs and the *BCBS* Plaintiffs omit entirely any reference to a particular state or states' laws. *See* IPP Compl., ¶¶ 353-356; BCBS Compl., ¶¶ 163-75. Rather, they simply aver generally, that "[i]n equity, Defendants should not be allowed to retain the economic benefit derived from said improper conduct and should be ordered to pay restitution and prejudgment interest to the [IPP] and Class members." IPP Compl., ¶ 356; *see* BCBS Compl., ¶ 175 (similarly asserting that "it would be unjust to allow King and Mutual to retain the benefits of [King's] sales of Skelaxin at illegally inflated prices."). These attempts at pleading generalized "federal common law" unjust enrichment claims are insufficient as a matter of law, and the Court should dismiss Claim VIII of the IPP Complaint and the Fourth Claim for Relief in the BCBS Complaint.

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[18] *See, e.g., In re Bank of Am. Credit Prot. Mktg. & Sales Practices Litig.*, 2012 WL 1123863, at *2 (N.D. Cal. Apr. 3, 2012) (dismissing unjust enrichment claims on a Rule 12(b)(6) motion and noting that "in order for an unjust enrichment claim to be adequately pled, the law under which the claim is brought must be specified in the complaint"); *In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 419 (E.D. Pa. 2009) (dismissing unjust enrichment claims on a 12(b)(6) motion for failure to specify a state's unjust enrichment law); *In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 536 F. Supp. 2d 1129, 1145 (N.D. Cal. 2008) (same); *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. 2d 1098, 1101 (N.D. Cal. 2007) (same).

B. The Unjust Enrichment Claims Fail Because They Seek to Circumvent the Limits of State Antitrust and Consumer Protection Laws

Plaintiffs have taken their antitrust and consumer protection allegations and recast the identical allegations as claims for "unjust enrichment." The only thing indentified as "unjust" about Defendants' alleged conduct is that it supposedly violated state antirust and consumer protection law. *See* IPP Compl., ¶¶ 353-57; EPP Compl., ¶¶ 346-58; BCBS Compl., ¶¶ 163-69. With this gambit, IPPs, EPPs, and the *BCBS* Plaintiffs hope to recover even if Defendants' conduct is found not to violate the substantive antitrust and consumer protection laws enacted by the states. This is entirely improper.

If Defendants' conduct does not violate the various states' substantive antitrust and consumer protection laws, then such conduct has been carved out by the states as permitted economic activity: "[t]he scope of antitrust laws and consumer protection statutes is designed to permit unfettered economic activity in matters that are not within their proscription." *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 209 (D. Me. 2004). To permit plaintiffs to nonetheless seek to punish such conduct under the rubric of "unjust enrichment" would warp state economic policy and "undermine state legislative policies and an entire body of substantive law." *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 542 n.13 (E.D. Pa. 2010). Substantive antitrust and consumer protection law would become meaningless if all such claims could be restyled as "unjust enrichment."

The law thus prevents Plaintiffs from circumventing the substantive limits of state antitrust and consumer protection laws by creatively dressing their claims as "unjust enrichment." *See, e.g., Sheet Metal Workers, Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 424-26 (E.D. Pa. 2010) (dismissing unjust enrichment claims by indirect purchasers because "[a]llowing such recovery would result in

circumvention of the policies expressed by state legislatures through the limitations inherent in these laws."); *In re New Motor Vehicles*, 350 F. Supp. 2d at 211 ("For those states that have maintained the *Illinois Brick* prohibition on indirect purchaser recovery, I conclude that it would subvert the statutory scheme to allow these same indirect purchasers to secure, for the statutory violation, restitutionary relief at common law (or in equity).").

The Court should dismiss the unjust enrichment claims pled in Claim VIII of the IPP Complaint, the Sixth Claim for Relief in the EPPs' Complaint, and the Fourth Claim for Relief in the BCBS Complaint.

IV. PLAINTIFFS' CLAIMS ARE BARRED BY THE STATUTES OF LIMITATIONS

A. Plaintiffs' Federal Antitrust Claims Are Time-Barred

Plaintiffs' federal antitrust claims are time-barred by the applicable four-year statute of limitations.[19] *See* 15 U.S.C. § 15b. Here, the first Plaintiff to assert federal antitrust claims -- Meijer -- filed its initial complaint on January 13, 2012. (Case No. 12-cv-181, Dkt. 1.) The remaining complaints asserting federal claims were filed between January and June 2012 and were then amended and consolidated in November 2012. The complaints allege that, absent Defendants' alleged conduct, generic metaxalone would have been on the market beginning sometime between 2005 and 2007 -- five to seven years before any claims were brought. *Supra*, pp. 8-9.

Because the complaints show on their face that Plaintiffs' federal antitrust claims are untimely, the Court should dismiss them. *See Jones v. Bock*, 549 U.S. 199, 215 (2007) (dismissing complaint that was untimely on its face); *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542,

[19] *See* Claims I-III of the DPPs' Complaint, the First Cause of Action in the EPPs' Complaint, and Claims I-III of the Walgreen Plaintiffs' Complaint.

547 (6th Cir. 2012) (same). And Plaintiffs' fraudulent concealment allegations do not save their claims because the acts about which Plaintiffs complain were matters of public record.

1. Plaintiffs Allege that Their Claims Accrued Between 2005 and 2007

"Under the Sherman Act, a cause of action must be commenced within four years of accrual." *Cipro*, 261 F. Supp. 2d at 218. "A cause of action accrues and the statute begins to run when a defendant commits an act that injures a plaintiff's business." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971).

The "discovery rule" does ***not*** apply to antitrust claims; instead, the Sherman Act's four-year statute of limitations is a "pure injury accrual rule." *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997); *see also Rotella v. Wood*, 528 U.S. 549, 557 (2000) (discovery rule "would clash with the limitations imposed on Clayton Act suits").

Here, all of Plaintiffs' claims are based on allegations that generic metaxalone was unlawfully excluded from the market. That is, Plaintiffs' claimed injury is that generic metaxalone would have been on the market earlier but for Defendants' conduct. Such claims accrue when the exclusion is alleged to have *begun* -- *i.e.*, when generic metaxalone allegedly should and would have been available but for the allegedly unlawful conduct. *See Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 271 (7th Cir. 1984) (Posner, J.) ("Exclusion from a market is a conventional form of antitrust injury that gives rise to a claim for damages as soon as the exclusion occurs . . . even though, in the nature of things, the [alleged] victim's losses lie mostly in the future."); *Kaiser Found. v. Abbott Labs.*, 2009 WL 3877513, at *7 (C.D. Cal. Oct. 8, 2009) (antitrust claim accrues when "generic manufacturers could and would have begun marketing a generic version" of the drug but for the allegedly anticompetitive conduct).

All of Plaintiffs' claims allege unlawful exclusion to have begun much earlier than January 13, 2008, *i.e.*, more than four years before even the first complaint was filed. As the

DPPs and EPPs straightforwardly allege, "but for the defendants' illegal conduct, generic metaxalone would have been available as early as November 4, 2005." DPP Compl., ¶ 257; *see* EPP Compl., ¶ 266. The *Walgreen* Plaintiffs similarly allege that "[t]he acts and practices of Defendants had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Skelaxin from generic competition from 2006 or 2007 until April 9, 2010." Walgreen Compl., ¶ 226. In their hundreds of pages of pleadings, Plaintiffs never allege an entry date later than January 2008.

The limited post-2008 events Plaintiffs allege do not save their claims. First, if a plaintiff's claim *accrued* outside the limitations period, the fact that the plaintiff may allege to have suffered *additional damage* within the limitations period is irrelevant. *See Zenith*, 401 U.S. at 339. In other words, if a claim is not asserted within four years of when it is alleged to have first accrued, the entire claim is time-barred regardless of how long damages allegedly continued. As the Supreme Court has explained, "if a Plaintiff feels the adverse impact of an antitrust conspiracy on a particular date, a cause of action immediately accrues to him to recover all damages incurred by the date and all provable damages that will follow in the future from the acts of the conspirators on that date." *Id.* For example, once conduct such as sham litigation or petitioning has caused injury, continuing that petitioning activity does not restart the statute of limitations. *See, e.g.*, 2 AREEDA & HOVENKAMP, *supra*, ¶ 320c4, at 299 (3d ed. 2007) (the "limitation period for monopolization by a wrongfully filed lawsuit . . . is not continued by subsequent pleadings, motions, trials, and the like").

Second, the post-2008 conduct Plaintiffs challenge could not have delayed the entry of generic metaxalone. Plaintiffs discuss the *Sandoz* patent litigation filed in December 2008, but that litigation did not result in a thirty-month stay of FDA approval of Sandoz's ANDA and

therefore could not have delayed the entry of generic Skelaxin (*i.e.*, caused Plaintiffs' injury). *Supra*, pp. 13-14.

Plaintiffs also challenge several FDA citizen petitions filed since January 2008. But in September 2007, a law was enacted to ensure that the filing of a citizen petition (sham or not) would not delay the FDA's consideration of an ANDA. *Supra*, pp. 6-7 & n.2. The new statute provides that the FDA "shall not delay approval of a pending [ANDA]" due to any pending citizen petition unless the FDA "determines, upon reviewing the petition, that a delay is necessary to protect the public health" -- something that did not occur here. 21 U.S.C. § 355(q)(1)(A). Thus, no citizen petition within the limitations period could have delayed FDA approval of an ANDA.

In short, Plaintiffs' antitrust claims accrued when generic versions of metaxalone would have been on the market but for Defendants' allegedly anticompetitive conduct -- according to Plaintiffs, in 2005, 2006, or 2007. All of Plaintiffs' complaints were filed more than four years after the latest such date. Even if Plaintiffs could allege that post-2008 acts increased their potential damages, that would not restart the limitations period. Therefore, the Court should dismiss the entirety of the DPPs' and *Walgreen* Plaintiffs' Complaints, as well as the First Cause of Action in the EPPs' Complaint, which pleads a federal antitrust claim.

2. Plaintiffs Do Not and Cannot Adequately Plead Fraudulent Concealment

Tacitly admitting that their claims would otherwise be time-barred, Plaintiffs contend that the statute of limitations should be tolled by alleged fraudulent concealment. DPP Compl., ¶¶ 296-99; Walgreen Compl., ¶¶ 236-38. To plead a claim for fraudulent concealment, Plaintiffs must allege facts showing: "(1) wrongful concealment of their actions by the defendants; (2) failure of the plaintiff to discover the operative facts that are the basis of his cause of action

within the limitations period; and (3) plaintiff's due diligence until discovery of the facts." *Dayco Corp. v. Goodyear Tire & Rubber Co.*, 523 F.2d 389, 394 (6th Cir. 1975).

a. Plaintiffs Cannot Plead the "Wrongful Concealment" Element of the *Dayco* Test

With regard to the wrongful concealment prong of the *Dayco* test, the complaints (together with judicially noticeable public records) demonstrate that Plaintiffs have not even pled *concealment*, much less wrongful concealment. The acts Plaintiffs complain of were all matters of public record and thus were not concealed in any way. A patent, the Orange Book listings of patents,[20] and patent litigation records[21] are all public documents. Citizen petitions, likewise, are public documents.[22] Plaintiffs nakedly assert that the 2005 License Agreement between King and Mutual was "self-concealing," but King filed the Agreement with the SEC in 2006, redacting only a few confidential terms.[23] *See* King Pharms., Inc., Annual Report (Form 10-K) Ex. 6 (Mar. 3, 2006).[24] Indeed, the existence and principal terms of the Agreement were publicly disclosed in a contemporaneous press release:

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[20] The Orange Book is "available to the public" and functions as "a catalog that informs the public of the [listed] patent's existence." *Merck & Co. v. MediPlan Health Consulting, Inc.*, 434 F. Supp. 2d 257, 264, (S.D.N.Y. 2006).

[21] "[P]rolonged litigation" and other such "matters of public record . . . must be held to have been within the knowledge" of the plaintiff. *Dayco Corp. v. Firestone Tire & Rubber Co.*, 386 F. Supp. 2d 546, 549 (N.D. Ohio 1974), *aff'd*, 523 F.2d 389 (6th Cir. 1975).

[22] *See* 21 C.F.R. § 10.20(j)(1) (petitions "will be on public display and will be available for public examination").

[23] The existence of King's SEC filings -- as well as the existence of other public records such as U.S. patents, citizen petitions filed with the FDA, and docket materials filed in federal litigation -- can be judicially noticed. *See, e.g.*, *Lynch v. Leis*, 382 F.3d 642, 647 n.5 (6th Cir. 2004) (publicly available court records are judicially noticeable); *In re UnumProvident*, 396 F. Supp. 2d at 875-76 (Collier, J.) (holding that the existence of statements contained in public disclosures filed with the SEC are judicially noticeable).

[24] *See* 2005 License Agreement, *available at* http://1.usa.gov/UqTHTx, (attached as *Exhibit* 6).

> [King] has entered into a co-exclusive license agreement with Mutual Pharmaceutical Company, Inc. Under the terms of the agreement, each of the parties has granted the other a worldwide license to certain intellectual property, including patent rights and know-how, relating to metaxalone. The intellectual property licensed to King relates to the potential for improved dosing and administration of metaxalone.
>
> Pursuant to the agreement, King will pay Mutual an upfront payment of $35 million and royalties on net sales of products containing metaxalone.

King Pharms., Inc., Current Report (Form 8-K) Ex. 99.1 (Dec. 9, 2005) (containing King's press release).[25]

Plaintiffs complain that Defendants "concealed their plan to prolong the Mutual '102 patent litigation" and "made relevant filings . . . under seal" in the '102 litigation. Walgreen Compl., ¶ 236; DPP Compl., ¶ 297. But, the stay of the Mutual '102 litigation, which is what Plaintiffs allege caused them harm, was also a matter of public record because the order memorializing the stay was (and is) in the public court file. *Supra*, p. 12 & n.8.

Finally, Plaintiffs allege that Defendants "concealed and failed to disclose their contractual arrangement to courts and to the FDA." Walgreen Compl., ¶ 236; DPP Compl., ¶ 297. Even if that were true, not providing the details of a public contractual arrangement to the courts and the FDA does not constitute fraudulent concealment *from Plaintiffs*. *See Pinney Dock & Transp. Co. v. Penn Cent. Corp.*, 838 F. 2d 1445, 1465 (6th Cir. 1988) (fraudulent concealment occurs only when "defendant's concealment *prevented plaintiff* from discovering the cause of action within the limitations period" (emphasis added)).

[25] *See* http://1.usa.gov/12U9AVL (attached as *Exhibit* 7). The Court can take judicial notice of this press release. *In re UnumProvident*, 396 F. Supp. 2d at 876 (Collier, J.) (taking judicial notice of a press release in deciding a Rule 12(b)(6) motion).

Plaintiffs have not identified any facts on which their complaints now rely that were not made public long ago. Even if Plaintiffs could identify such concealment, they have failed to plead anything *wrongful*: "[m]ere silence or unwillingness to divulge wrongful activities is not sufficient" to establish wrongful concealment. *Carrier Corp. v. Outokumpu Oyi*, 673 F.3d 430, 447 (6th Cir. 2012). "Instead, there must be some trick or contrivance intended to exclude suspicion and prevent inquiry." *Id.* at 446-47 (internal quotation marks omitted). This is a high bar: when a plaintiff pleads fraudulent concealment, "[a]ll presumptions are against him, since his claim to exemption is against the current of the law and is founded on exceptions." *Akron Presform Mold Co. v. McNeil Corp.*, 496 F.2d 230, 233 (6th Cir. 1974).

Plaintiffs fail to meet this wrongful concealment prong. They allege only that Defendants' conduct was "self-concealing" and that Defendants employed "deceptive practices and techniques of secrecy . . . to avoid detection of, and fraudulently conceal, their contact, combination, conspiracy, and scheme." DPP Compl., ¶ 297; Walgreen Compl., ¶ 236. Such conclusory labels do not satisfy Rule 9(b), which applies to allegations of facts giving rise to fraudulent concealment because fraudulent concealment is a type of fraud. *See Dayco*, 523 F.3d at 389. Rule 9(b) requires Plaintiffs to "specify 'the time, place and content of the alleged' fraudulent acts." *Carrier*, 673 F.3d at 447. They have not done so.

Plaintiffs also have failed to allege that the supposed "concealment" of these *publicly available documents* was fraudulent in any way -- let alone with the specificity required by Rule 9(b). For example, Plaintiffs fail to identify the facts supposedly concealed, what wrongful acts Defendants supposedly took to conceal those facts, or when, in Plaintiffs' view, these facts should have become known. As described above, mere silence or mere nondisclosure does not establish fraudulent concealment; instead, Plaintiffs must show that Defendants took affirmative

steps, such as destroying documents or lying about them. *See, e.g.*, *Michigan ex. Rel. Kelley v. McDonald Dairy Co.*, 905 F. Supp. 447, 452 (W.D. Mich. 1996) (allegations of "providing false information to law enforcement authorities," "destroying documents," and "concealing public records" established fraudulent concealment).

b. Plaintiffs Fail to Plead the "Due Diligence" Element of the *Dayco* Test

Plaintiffs also fail to meet their burden to allege facts supporting the third prong of the *Dayco* test, that they were diligent about discovering the alleged facts. *See Pinney*, 838 F.2d at 1465 ("The burden of proving the elements of fraudulent concealment is upon plaintiff."); 2 AREEDA & HOVENKAMP, *supra*, ¶ 320, at 320 ("[A] plaintiff who has not exercised due diligence may not benefit from alleging fraudulent concealment.").

Plaintiffs allege merely that they "had no knowledge of the alleged conspiracy, or of any facts or information that would have caused a reasonably diligent person to investigate whether a conspiracy existed, until . . . 2010 at the earliest." DPP Compl., ¶ 298; Walgreen Compl., ¶ 237. That is simply not good enough; Plaintiffs' alleged lack of knowledge is pointedly not an allegation that they were diligent. Nor could Plaintiffs plausibly allege diligence, given that all of the underlying acts, as previously noted, were conducted entirely in the public sphere. Where publicly disclosed activities, such as those Plaintiffs have alleged, "should have aroused [Plaintiffs'] suspicions," their "failure to investigate further at that time was not the exercise of due diligence required in order to employ the fraudulent concealment doctrine." *Dayco*, 523 F.2d at 394. Everything Plaintiffs rely on now was available to them within the statutory period.

The fraudulent concealment allegations should be dismissed, and Plaintiffs therefore cannot escape the fact that their federal antitrust claims are time-barred.

B. Plaintiffs' State Claims Are Time-Barred

Most of the state statutory-based claims brought by the EPPs, IPPs, and *BCBS* Plaintiffs are time-barred for the same reasons as the federal claims.[26]

1. EPPs', IPPs', and *BCBS* Plaintiffs' Claims are Time-Barred Under State Statutes That Measure the Statute of Limitations Period from Date of Injury

Plaintiffs' state claims are barred under those laws that, like federal antitrust law, measure accrual from the date of injury: the antitrust claims under the laws of Arizona, California, Florida, Kansas, Michigan, Minnesota, Nebraska, New York and North Carolina, and the consumer protection claims under the laws of Arkansas, California, Nebraska and New York.[27] As with the Sherman Act, the "discovery" rule does not apply to these state statutes.

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[26] The state statutory claims are pled in Claims I-VI of the IPPs' Complaint, the Second to Fifth Claims for Relief in the EPPs' Complaint, and the First, Second, Third, and Fifth Claims of the BCBS Complaint.

[27] Ariz. Rev. Stat. § 44-1410 (action "is barred if it is not commenced within four years after the cause of action accrues"); Cal. Bus. & Prof. Code § 17208 (action "shall be commenced within four years after the cause of action accrued); Fla. Stat. § 95.11(3)(f) (an "action founded on a statutory liability" shall be commenced within four years); K.S.A. § 60-512(2) ("An action upon a liability created by a statute other than penalty or forfeiture" shall be brought within three years); Mich. Comp. Laws Ann. § 445.781 (action "barred if not commenced within 4 years after the claim of relief or cause of action accrues"); Minn. Stat. § 325D.64 (action "forever barred unless commenced within four years of the date upon which the cause of action arose"); Neb. Rev. Stat. § 25-212 (applying four-year period to actions with unspecified limitations period); N.Y. Gen. Bus. Law § 340(5) ("An action to recover damages caused by a violation of this section must be commenced within four years after the cause of action has accrued."); N.C. Gen. Stat. § 75-16.2 (action "barred unless commenced within four years after the cause of action accrues"); Ark. Code § 4-88-115 (action may be brought "during a period of five (5) years commencing on the date of the occurrence of the violation or the date upon which the cause of action arises"); Cal. Bus. & Prof. Code § 16750.1 (action "shall be commenced within four years after the cause of action accrued"); Neb. Rev. Stat. § 59-1612 (action "shall be forever barred unless commenced within four years after the cause of action accrues"); N.Y. C.P.L.R. § 214 ("[A]n action to recover upon a liability, penalty or forfeiture created or imposed by statute" commences within three years); *see also M&T Mortgage Corp. v. Miller*, 2009 WL 3806691, at *1-2 (E.D.N.Y. Nov. 13, 2009) (applying three-year period of limitations for statutory causes of action under N.Y. C.P.L.R. 214(2) to N.Y. Gen. Bus. Law § 349 claims).

Rather, the period begins to run when a defendant commits an act that is alleged to have injured the plaintiff.[28]

An action must be commenced within four years after the cause of action accrues under the antitrust statutes of Arizona, California, Florida, Michigan, Minnesota, Nebraska, New York, and North Carolina, as well as the consumer protection statutes of California and Nebraska. *Supra*, n.27. Kansas's antitrust statute and New York's consumer protection statute require that actions be commenced within three years. *Supra*, n.27. Arkansas's consumer protection statute provides for a five-year accrual period. *Supra*, n.27.

As with the federal claims discussed above, Plaintiffs' state-law claims accrued when, according to Plaintiffs' allegations, Defendants unlawfully excluded generic metaxalone from the market, *i.e.*, the date of Plaintiffs' alleged injury. *See, e.g., supra*, n.28.

Because the EPPs, IPPs, and *BCBS* Plaintiffs allege that generic versions of metaxalone should have been on the market in 2005, 2006, or 2007, Plaintiffs' claims necessarily accrue no

[28] *See, e.g., El Aguila Food Prods. v. Gruma Corp.*, 301 F. Supp. 2d 612, 618 (S.D. Tex. 2003) (holding that state statutory claims were time-barred because under Arizona, California and Michigan antitrust statutes, claims "must be brought within four years of the injury that gives rise to the cause of action"); *Perez v. Nidek Co.*, 657 F. Supp. 2d 1156, 1166 (S.D. Cal. 2009) (interpreting Cal. Bus. & Prof. Code §§ 17200 *et seq.*, which provides that a cause of action must be commenced "within four years after the cause of action accrued," to mean that claims under the statute are subject to a four-year limitation which begins to run on the date the cause of action accrues, not on the date that the injury was discovered); *McKissic v. Country Coach, Inc.*, 2008 WL 2782678, at *8 (M.D. Fla. July 16, 2008) (holding that the Florida Deceptive and Unfair Trade Practices Act was governed by a four year statute of limitations under Fla. Stat. § 95.11 and the delayed discovery rule does not apply); *Culp v. Sifers*, 533 F. Supp. 2d 1119, 1127 (D. Kan. 2008) (finding plaintiff's reliance on discovery rule was without merit in the context of the three-year statute of limitations period provided in K.S.A. § 60-512(2)); *Mangan v. Landen*, 219 Neb. 643, 645-646 (1985) (holding that under Neb. Rev. Stat. § 25-212, the statute of limitations begins to run when plaintiff has the right to bring suit, even though plaintiff may be unaware of the existence of a cause of action); *Hinson v. United Fin. Servs.*, 123 N.C. App. 469, 475 (1996) ("a cause of action pursuant to [N.C. Gen. Stat.] § 75-16 accrues when the violation occurs"); *M&T Mortgage Corp.*, 2009 WL 3806691, at *1-2 (finding that accrual of a private right of action under New York's consumer protection statute first accrues when plaintiff has been injured).

later than those dates. *Supra*, pp. 38-40. Plaintiffs' allegations of fraudulent concealment for their state law claims are no more successful than the allegations relating to the federal claims.

2. The EPPs', IPPs', and *BCBS* Plaintiffs' Claims are Also Time-Barred Under State Statutes that May Apply a Discovery Rule

Even where state limitations periods may begin to run on the date the injury was, or with reasonable diligence, should have been, discovered, Plaintiffs' claims are still time-barred. Thus, Plaintiffs' claims are also time-barred under the laws of Massachusetts, Mississippi, Nevada, New Mexico and West Virginia, as well as the consumer protection statutes of Massachusetts,[29] Missouri, and Virginia. All of these statutes have limitations periods that begin to run on the date the injury was, or with reasonable diligence, should have been, discovered. As noted above, the acts that Plaintiffs allege injured them were all public. *Supra*, pp. 41-44. Therefore, the date of the alleged injury (*i.e.*, the date generic metaxalone would have entered the market in the but-for world) should have been discovered with reasonable diligence when it occurred (whether in 2005, 2006 or 2007). *See, e.g.*, DPP Compl., ¶¶ 176, 195-96, 257; Walgreen Compl., ¶¶ 144, 149, 150, 226.

[29] EPPs bring both antitrust and consumer protection claims under the consumer protection statute Mass. Ann. Laws ch. 93A. The statute of limitations period applies to both the antitrust and consumer claims brought by EPPs.

Under the statutes of Massachusetts, Nevada, New Mexico, and West Virginia, the statute of limitations period is four years.[30] Mississippi's antitrust law provides for a three-year period of limitation.[31] Virginia's consumer protection statute requires that an action be brought within two years.[32] Finally, Missouri's consumer protection statute is governed by a five-year period that is triggered not when the injury is discovered, but when the injury could have reasonably been discovered.[33]

While the discovery rule is not identical to tolling based on fraudulent concealment, Plaintiffs' fraudulent concealment allegations set forth their only potential basis for avoiding a

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[30] *See* Mass. Ann. Laws ch. 260, § 5A (providing for statute of limitation period of four years for actions arising under consumer protection laws); *Lambert v. Fleet Nat'l Bank*, 449 Mass. 119, 126 (2007) (applying the discovery rule to Mass. Ann. Laws ch. 93A claim, subject to tolling until plaintiff knew or should have known about the alleged injury); Nev. Rev. Stat. Ann. § 598A.220(1), (2)(a) (action barred if not commenced within four years of accrual, or "if the cause of action is based upon a conspiracy in violation of this chapter, within 4 years after the plaintiff discovered, or by the exercise of reasonable diligence, should have discovered the facts relied upon for proof of the conspiracy"); N.M. Stat. Ann. § 57-1-12 (action "barred if it is not commenced within four years after the cause of action accrues or within four years after the plaintiff discovered, or by the exercise of reasonable diligence should have discovered, the facts relied upon for proof of the cause of action, whichever is later"); W. Va. Code § 47-18-11 (action barred if not commenced within four years of accrual, or "if the cause of action is based upon a conspiracy in violation of this article, within four years after the plaintiff discovered, or by the exercise of reasonable diligence should have discovered the facts relied upon for proof of the conspiracy").

[31] *See* Miss. Code Ann. §§ 75-21-3 *et seq.*; *Carder v. BASF Corp.*, 919 So. 2d 258, 261-62 (Miss. Ct. App. 2005) (statute of limitations for an antitrust claim "commences on the date of discovery, or when with due diligence, the injury could have been discovered").

[32] *See* Va. Code Ann. § 59.1-204.1(A); *Schaefer v. Tectonics, II, Ltd.*, 77 Va. Cir. 1, 3 (Va. Cir. Ct. 2008) (statute of limitations for the Virginia Consumer Protection Act commences "on the date of discovery, or the date when pursuant to the exercise of due diligence it reasonably could be discovered").

[33] *See* Mo. Rev. Stat. § 516.120(2) (applying five-year statute of limitations for "[a]n action upon a liability created by a statute other than a penalty for forfeiture"); *Ball v. Friese Const. Co.*, 348 S.W. 3d 172, 176 (Mo. Ct. App. 2011) (applying Mo. Rev. Stat. § 516.120 to Missouri Merchandising Practices Act, finding that the five-year period is not triggered when the alleged damage is discovered, but rather when damage is sustained and becomes capable of ascertainment).

time-bar under the discovery rule if the limitations period began at the time that the alleged injury should have reasonably been discovered. EPP Compl., ¶¶ 295-297; IPP Compl., ¶¶ 297-299; BCBS Compl. ¶¶ 142-44. Plaintiffs offer only the conclusory assertion that they could not have discovered the information "that would cause a reasonably diligent person to investigate whether a conspiracy existed" until early 2010, when SigmaPharm, Inc. ("SigmaPharm") filed its complaint. EPP Compl., ¶ 297; IPP Compl., ¶ 299; BCBS Compl., ¶ 143. But the alleged injurious acts were matters of public record earlier than 2007; Plaintiffs do not point to any specific alleged acts that they learned from SigmaPharm's complaint that they could not reasonably have learned earlier. Moreover, Plaintiffs give no indication that they exercised any efforts whatsoever -- let alone reasonable due diligence, to "discover" the facts they now rely upon in their complaints. *Supra*, p. 44.

For these reasons, the Court should dismiss Claims I-VI of the IPPs' Complaint and the Second, Third, Fourth and Fifth Claims for Relief of the EPPs' Complaint, and the First, Second, Third, and Fifth Claims for Relief of the BCBS Complaint.

CONCLUSION

For the following reasons, Defendants respectfully request that the Court dismiss the Complaints filed by the DPPs, the IPPs, the EPPs, the *Walgreen* Plaintiffs, and the *BCBS* Plaintiffs:

1. Plaintiffs' federal joint conduct claims fail to allege causation, and Defendants' alleged actions are, in any event, protected by the First Amendment;

2. The IPPs' Tennessee Trade Practices Act fails to allege facts showing that Defendants' allegedly wrongful conduct had "substantial effects" on Tennessee trade or commerce;

3. The unjust enrichment claims suffer from numerous infirmities; and

4. Plaintiffs' claims are time-barred, and the doctrine of fraudulent concealment is not applicable here.

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/s/ Saul P. Morgenstern
SAUL P. MORGENSTERN
KARIN E. GARVEY
Kaye Scholer LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-7210
Fax: (212) 836-6333

AUBREY B. HARWELL, JR.
GERALD D. NEENAN
JEFFREY H. GIBSON
Neal & Harwell, PLC
150 4th Avenue North
Suite 2000
Nashville, TN 37219
Tel: (615) 244-1713
Fax: (615) 726-0573

Attorneys for King Pharmaceuticals LLC, f/k/a King Pharmaceuticals, Inc.

/s/ Michael J. Klisch
MICHAEL J. KLISCH
Cooley LLP
1299 Pennsylvania Ave., N.W.
Suite 700
Washington, DC 20004-2400
Tel: (202) 842-7800
Fax: (202) 842-7899

ROBERT T. CAHILL
JONATHAN S. LAWSON
Cooley LLP
11951 Freedom Drive
Reston, VA 20190
Tel: (703) 456-8000
Fax: (703) 456-8100

JEFFREY I. WEINBERGER
ROHIT K. SINGLA
Munger Tolles & Olson LLP
355 South Grand Ave.
35th Floor
Los Angeles, CA 90071
Tel: (213) 683-9100

C. CELESTE CRESWELL
ZACHARY H. GREENE
Miller & Martin, PLLC
832 Georgia Avenue
Suite 1000 Volunteer Building
Chattanooga, TN 37402
Tel: (423) 756-6600
Fax: (423) 785-8480

Attorneys for Mutual Pharmaceutical Company, Inc.

CERTIFICATE OF SERVICE

I certify that on January 4, 2013, a copy of Defendants' Memorandum in Support of the Motion to Dismiss Plaintiffs' Complaints was served electronically on counsel of record for all parties through the Court's CM/ECF system.

Dated: January 4, 2013

/s/ Michael J. Klisch
MICHAEL J. KLISCH
Cooley LLP
1299 Pennsylvania Ave., N.W.
Suite 700
Washington, DC 20004-2400
Tel: (202) 842-7800
Fax: (202) 842-7899

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